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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/321,882	05/28/99	UPASANI	R 1483.0130002

HM12/1129
STERNE KESSLER GOLDSTEIN AND FOX PLLC
SUITE 600
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3934

EXAMINER

RADIO, B

ART UNIT	PAPER NUMBER
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1616

13

DATE MAILED:

11/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/321,882

Applicant(s)

Upasani et al.

Examiner

Barbara Badio

Group Art Unit

1616

☐ Responsive to communication(s) filed on _____.

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 25-27, 46, 55, 57-59, and 61-67 is/are pending in the application.

Of the above, claim(s) 63, 66, and 67 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25-27, 46, 55, 57-59, 61, 62, 64, and 65 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Final Office Action on the Merits

Status of the Application

1. Claims 25-27, 46, 55, 57-59 and 61-67 are pending in the present application. Claims 63, 66 and 67 stand withdrawn from further consideration as being drawn to a non-elected invention. Claims 25-27, 46, 55, 57-59, 61, 62, 64 and 65 will be examined to the extent they read on the elected species and obvious variants thereof.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

3. The objection of claim 25 under 37 CFR 1.75(c) is withdrawn.

Claim Rejections - 35 USC § 103

4. The rejection of claims 25, 26, 46, 55, 57, 58 and 61 under 35 USC 103(a) over Phillipps et al. ('345) is withdrawn.
5. Claims 25-27, 46, 55, 57, 59 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gee et al. (WO 94/27608).

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Gee et al. teach compounds and compositions containing 3 α -hydroxy pregnanes derivatives, such as 3 α -hydroxy-21(pyrid-4-ylthio)-5 β -pregnan-20-one (see page 13, line 17), useful for induction of sleep (see the entire article, especially pages 10-13).

The instant claims differ from the reference by reciting 3 α -hydroxy-21(pyrid-4-ylthio)-5 β -pregnan-20-one derivatives having a substituent other than hydrogen or alkyl in the 3 β -position. However, Gee et al. teach substitution in the 3 β -position and an equivalence between hydrogen, lower alkyl groups such as methoxymethyl, lower alkynyl groups such 4-hydroxypent-1-ynyl, (4'-acetylphenyl)ethynyl and ethynyl (see page 11, formula I and lines 9-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make the compound exemplified by Gee having any of the above mentioned substituents taught by the prior art with the reasonable expectation that the compound produced would have similar properties as taught by Gee et al.

6. Claims 25-27, 46, 55, 57-59, 61 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolger et al. ('917).

Bolger et al. teach a generic group of steroidal derivatives for modulating animal brain excitability via the GABA receptor-chloride complex (see col. 5, line 50 - col. 11, line 19). The reference teaches compounds wherein R₈ is -C(O)-CH₂-O-R₁₆ and R₁₆ is a C₅-C₁₀ aromatic radical or C₃-C₁₀ heterocyclic radical (col. 8, lines 5-16).

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The instant claims differ from the reference by reciting a more limited genus than the reference (i.e. compounds having an acetyl derivative in the 17-position). However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. The motivation to make other species taught by Bolger is based on the desire to make additional compounds useful in modulating animal brain excitability via the GABA receptor-chloride complex.

Allowable Subject Matter

7. The examiner notes applicant's comments on the allowability of claims 27 and 59. However, it is noted that the claims were said to be allowable to the extent they read on the elected species. The search of the instant invention has been extended and the instant claims are now rejected as indicated above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

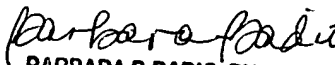
Telephone Inquiry Contacts

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

November 27, 2000


BARBARA P. BADIO, PH.D.
PRIMARY EXAMINER